

FILED

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U.S. COURT OF APPEALS

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

FUSION IV PHARMACEUTICALS,  
INC., DBA Axia Pharmaceutical, a  
California corporation; NAVID VAHEDI,  
Pharm D.,

Plaintiffs-Appellants,

v.

ANNE SODERGREN, in her Official  
Capacity as the Interim Executive Officer  
of the California State Board of Pharmacy,

Defendant-Appellee,

and

CALIFORNIA STATE BOARD OF  
PHARMACY; et al.,

Defendants.

No. 19-55791

D.C. No.  
2:19-cv-01127-PA-FFM

MEMORANDUM\*

Appeal from the United States District Court  
for the Central District of California  
Percy Anderson, District Judge, Presiding

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\* This disposition is not appropriate for publication and is not precedent  
except as provided by Ninth Circuit Rule 36-3.

Submitted June 1, 2020\*\*  
Pasadena, California

Before: RAWLINSON and N.R. SMITH, Circuit Judges, and KORMAN,\*\*  
District Judge.

Fusion IV Pharmaceuticals, Inc. (“Fusion IV”) appeals the district court’s grant of judgment on the pleadings. Fusion IV argues that California’s regulatory requirements: (1) are preempted by the Drug Quality and Security Act (“DQSA” or “Act”), *see* Drug Quality and Security Act, Pub. L. No. 113–54, 127 Stat. 587–640 (2013); or, alternatively, (2) violate the Commerce Clause’s protections against state laws that unreasonably burden Federal law. We have jurisdiction under 28 U.S.C. § 1291, and we affirm.<sup>1</sup>

1. The district court properly found there was no preemption. *McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1039 (9th Cir. 2015).

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\*\* The panel unanimously concludes this case is suitable for decision without oral argument. *See* Fed. R. App. P. 34(a)(2).

\*\*\* The Honorable Edward R. Korman, United States District Judge for the Eastern District of New York, sitting by designation.

<sup>1</sup> The motion of the National Association of Boards of Pharmacy, the Arkansas State Board of Pharmacy, the Kansas State Board of Pharmacy, the Louisiana Board of Pharmacy, the Michigan Board of Pharmacy, the Mississippi Board of Pharmacy, the North Dakota State Board of Pharmacy, the State of Ohio Board of Pharmacy, and the Oklahoma State Board of Pharmacy for leave to file a brief in support of Defendant–Appellee as *amicus curiae*, *see* Dkt. 24, is also granted.

A. There is no express preemption, because the DQSA does not “explicitly manifest[] Congress’s intent to displace state law” dealing with mass compounding. *Valle del Sol Inc. v. Whiting*, 732 F.3d 1006, 1022 (9th Cir. 2013) (quoting *United States v. Alabama*, 691 F.3d 1269, 1281 (11th Cir. 2012)). Thus, there can be no express preemption by negative implication, because express preemption, by its very definition, cannot be implied. *See Gadda v. Ashcroft*, 377 F.3d 934, 944 (9th Cir. 2004).

B. There is also no field preemption, because “the scheme of federal regulation” at issue here is not “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.” *Gade v. Nat’l Solid Wastes Mgmt. Ass’n*, 505 U.S. 88, 98 (1992) (internal quotation marks omitted) (quoting *Fidelity Fed. Sav. & Loan Ass’n. v. de la Cuesta*, 458 U.S. 141, 153 (1982)). Because the DQSA clearly allows for “complementary state regulation[s],” Fusion IV’s field preemption claims fail. *See Arizona v. United States*, 567 U.S. 387, 401 (2012).

C. There is no conflict preemption, because it is not “impossible for a private party to comply with both state and federal [compounding] requirements.” *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Importantly, it is possible to obtain authorization under both the state and federal regulatory schemes, because

California does not necessarily require anything more than registration with the FDA before a facility can acquire a state license. *See* Cal. Bus. & Prof. Code § 4129.1(d)(2).

2. The district court properly found that the applicable California licensing requirements do not violate dormant Commerce Clause principles. Fusion IV failed to establish that the requirements impose a “substantial burden” on interstate commerce. *See Nat’l Ass’n of Optometrists & Opticians v. Harris*, 682 F.3d 1144, 1148 (9th Cir. 2012).

**AFFIRMED.**